

Serial No.: 09/586,510  
Docket No.:503775.0008

### **REMARKS/ARGUMENTS**

Claims 1, 3-15 remain pending in this application. Claims 8-12 have been withdrawn.  
Claims 2, 16-26 have been canceled. Claim 1 has been amended.

The amendment to Claim 1 and cancellation of Claims 21-26 are made without prejudice, to put the claims in condition for allowance or in better form for appeal. As such the amendments comply with 37 C.F.R. § 1.116, and entry of such amendments is requested. Applicant reserves the right to pursue the cancelled subject matter in a continuation or divisional application.

### **Request to Delete Inventor**

Applicant's request to delete inventor Leneau is resubmitted herewith, signed by a party set forth under 1.33(b), namely an attorney of record, as required. Acceptance of the request is respectfully requested.

### **Support in the Specification as Originally Filed for the Claimed Inventions**

The Examiner rejected claim 1-7, 13-15 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The present amendment renders such rejections moot. Such amendment was made to expedite prosecution and to put the claims in condition for allowance. Applicant does not agree with the Examiner's rejection and reserves the right to pursue claims directed to "exercise induced pulmonary hemorrhage per se," "respiratory disease complex resulting from shipment or crowding," "upper respiratory infections accompanying stress," "and/or combinations thereof" in continuation and/or divisional applications.

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**The Claims Are Enabled by the Specification**

The Examiner rejected claims 1-7, 13-15 under 35 U.S.C. § 112, first paragraph, arguing the specification is not enabling for the claimed method of treating exercise induced pulmonary hemorrhage (EIPH). Specifically, the Examiner argued that there is no evidence that the invention could be successfully used to treat EIPH. Applicant submits that the specification would enable one of ordinary skill in the art to practice the full breadth of the claimed invention and respectfully traverses the Examiner's rejection.

Applicant submits herewith the declaration of Dr. Howard Erickson, entitled "Declaration III of Howard Erickson," ("Erickson III"), who has utilized Ig compositions to successfully treat EIPH. (Erickson III, ¶¶ 7-10). The Erickson III declaration provides details regarding the materials and methods utilized, as requested by the Examiner. (Erickson III, ¶¶ 8-9). Specifically, Dr. Erickson used the Ig composition sold under the trademark SERAMUNE EQUINE IgG. (Erickson III, ¶ 8). As noted by Dr. Erickson, SERAMUNE EQUINE IgG is an equine serum concentrate that contains IgG as well as other immunoglobulins. (Erickson III, ¶ 8). The composition is labeled as an IgG composition because it is sold for treatment of failure of passive transfer, wherein efficacy is measured by measuring IgG content. Thus, although it is marketed as an "IgG" composition, SERAMUNE EQUINE IgG contains ADDITIONAL immunoglobulins found in equine serum.

Dr. Erickson states that he has statistically significant, documented evidence that the administration of Ig compositions can be used as an effective treatment for EIPH (Erickson III, ¶ 7), and provides a summary of such evidence. (Erickson III, ¶ 10). Based on these results, Dr. Erickson is able to state that his evidence establishes that the administration of Ig is an effective treatment for EIPH. (Erickson III, ¶ 10).

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Further, Dr. Erickson indicates that while the mechanism of action in EIPH is unclear, and there are various factors involved, EIPH is believed to be immune regulatory in origin. (Erickson III, ¶ 15). Applicant submits that Dr. Erickson's statements in his declaration, supported by direct test results and eight additional years of experience, are more probative as to the efficacy and predictability of the use of Ig compositions to treat EIPH than the statement made in his 1995 paper, cited by the Examiner. This is particularly true in view of the fact that Dr. Erickson expressly acknowledges the statements made in his 1995 paper (Erickson III, ¶ 14), and still comes to the conclusion that the administration of Ig compositions is an effective treatment for EIPH. (Erickson III, ¶ 10)

In view of the foregoing, Applicant submits that the specification of the present application would enable one skilled in the art to use Ig compositions for the treatment of EIPH in horses without undue experimentation. As a result, Applicant respectfully submits that the specification enables the full breadth of the claims, and requests removal of the rejection under 35 U.S.C. 112, first paragraph.

**Ragland et al. Is Not a Prior Art Reference**

The Examiner has rejected claims 1, 5, 6, 13-15 under 35 U.S.C. 102(a) as being anticipated by Ragland et al. Applicant respectfully submits that the Ragland et al. reference is not prior art under 102(a), insofar as Ragland et al. derived their knowledge of the claimed invention from the inventor of the present application. In support of this contention, Applicant submits a revised declaration of the inventor, entitled "Declaration II of William G. Skelly" ("Skelly II"). The Skelly II declaration has been clarified to address the concerns raised by the Examiner regarding the first Skelly declaration, specifically to clarify that Mr. Skelly does not claim to be a co-author of the Ragland et al. reference (Skelly II, ¶ 5) and to clarify that Mr.

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Skelly communicated the invention to Harry Leneau, who in turn communicated it to the authors.  
(Skelly II, ¶ 4)

When the subject matter disclosed in a publication is the applicant's own invention or is attributable to the applicant, a rejection may be removed by submission of evidence establishing that the author of the publication derived his knowledge of the relevant subject matter from the applicant. M.P.E.P. §§ 715.01(c); 716.10. Mr. Skelly's uncontroverted declaration establishes that Ragland et al. derived knowledge of the method of using Ig to treat equine respiratory infections from Mr. Skelly. (Skelly II, ¶ 4). The Skelly II Declaration further establishes that it was Mr. Skelly who invented the subject matter disclosed in the publication. (Skelly II, ¶¶ 1, 4).

The Skelly II declaration is uncontradicted and unequivocal, and as such should be accepted under M.P.E.P. 716.10. In fact, the declaration is corroborated by the fact that Ragland et al. expressly acknowledge that the Ig composition used in their experiments was obtained from Applicant's company, Sera, Inc. (column 1, page 2 of Ragland et al.; Skelly II, ¶ 2). As such, Mr. Skelly has provided satisfactory showing by way of affidavit under 37 C.F.R. 1.132 that the reference discloses subject matter derived from Mr. Skelly, rather than invented by the author, pursuant to M.P.E.P. 715.01(c) and 716.10.

Furthermore, Applicant finds no requirement in In re Katz, 215 U.S.P.Q. 14 (CCPA 1982), M.P.E.P. 715.01(c) or 716.10 that only references co-authored by the applicant can be overcome by a declaration under § 1.132. In fact, Example 2 in M.P.E.P. 716.10 indicates that that if the author is an "entity different from the applicant," as is the present case, an affidavit under 37 C.F.R. § 1.132 may be submitted to show that the relevant portions of the reference originated with or were obtained from applicant. That is precisely what the Skelly II

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Declaration shows in the present case. As a result, Applicants respectfully request removal of the rejection over Ragland et al.

**Priority Claim**

The Examiner has indicated that Applicant's claim of priority extends only to parent application 08/685,052 and not to parent application 08/349,010. Applicant submits that it is able to overcome the Examiner's rejections without relying on the filing date of parent application 08/349,010. Thus, consideration of Applicant's claim of priority is unnecessary at this time. However, Applicant reserves the right to assert and establish its right to the priority claim in the future.

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1, 3-7 and 13-15 are now in condition for allowance and eventual issuance. Such action is respectfully requested. Furthermore, insofar as generic claims 1 and 6 are allowable, withdrawn claims 8-12, which include all of the limitations of Claims 1 and 6, should be allowed, and such action is respectfully requested.

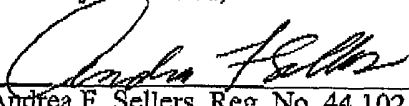
Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, he is invited to contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

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Respectfully submitted,

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